Cahoy Dec. Ex. 5

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION
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IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION, Case No. 3:21-cv-03825-VC
THIS DOCUMENT RELATES TO: ALL CASES
_____/

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff,

vs. Case No. 3:21-cv-03496-VC

INTUITIVE SURGICAL, INC.,

Defendant.
_____/

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

VIDEO-RECORDED DEPOSITION OF MARGARET MARIE NIXON
VERITEXT VIRTUAL
FRIDAY, OCTOBER 7, 2022

Reported by:
Anrae Wimberley, CSR No. 7778
Job No. 5507214

technology?

MS. CAHOY: Objection to form.

THE WITNESS: From the clinical development perspective, not in the physical design.

BY MR. SINDONI:

Q. And what was your involvement from the clinical development perspective?

A. My involvement was ensuring that the instruments were being registered accordingly and -- when they were being used in clinically representative scenarios.

Q. Do you know who at Intuitive was primarily responsible for developing that technology from an engineering perspective?

A. Oh, man, I don't know the primary. There was a dozen.

Q. A dozen.

Any of that dozen that you recall today?

A. Not that I recall.

Q. Do you have any understanding of why Intuitive switched the technology that limits the uses of instruments in the Si instruments to the different RF chip in the Xi instruments?

A. Are you asking why we changed from the electrical chip interface into the radio frequency?

Q. Yes, that is a better question than I asked, and that is what I'm asking.

A. It was -- it was my recollection that we did that to ensure we had good consistency. When you rely on electrical contacts, sometimes you could have inconsistencies on detection. And the radio frequency intent was that we would have a more reliable communication.

Q. Besides the technology we've discussed so far, do you have knowledge of whether Intuitive has considered implementing other technological means to prevent EndoWrist from being used beyond the use limits set by Intuitive?

MS. CAHOY: Objection to form.

THE WITNESS: I'm sorry, I'm not sure I understood that question.

BY MR. SINDONI:

Q. Sure.

We've discussed the RF technology used in the Xi instruments; correct?

A. Yes.

Q. And we discussed the physical chip used in the Si instruments; correct?

A. Yes.

Q. Beyond those two chips, has Intuitive

Q. Putting the clip appliers aside, are there other instruments you're aware of that did not have a 10-use limit?

A. At the time they were launched?

Q. Yes.

A. I don't recall the details of exactly how many lives each of the instruments had. There was just such a wide variety.

Q. Do you have an understanding of how Intuitive set the use limit for EndoWrist instruments at 10 uses?

MS. CAHOY: Objection to form.

THE WITNESS: What time frame are you referring to?

BY MR. SINDONI:

Q. Fair enough. Going back -- let's go back to the Si instruments.

Do you have an understanding of how those instruments were set at a 10-use limit?

MS. CAHOY: Objection to form.

THE WITNESS: Yes.

BY MR. SINDONI:

Q. And what's your general understanding of how those use limits were set?

A. So for each of the instruments, there is

an instrument architecture associated with it. There is a -- control parameters, how the instrument is driven, and a clinical use scenario that goes with each of the instruments, because they complete different surgical tasks.

And so the combination of those three things were assessed to determine how we can ensure kind of consistent safety and efficacy of the instrument over the course of the lives of the instrument. And those came together to determine the lifes [sic] that came on the instrument.

Q. And did Intuitive do any testing of the expected life of the instruments?

A. Yes.

Q. And were you involved in that testing?

A. Yes.

Q. In your role as an engineer; correct?

A. Yes.

Q. If you can turn to -- you have a folder of exhibits with you; correct?

A. Yes.

Q. I'm going to --

THE WITNESS: Are these both the same?

MS. CAHOY: Yes.

THE WITNESS: Okay.

Q. Okay. And based on your experience as an engineer involved in life testing at Intuitive, is this protocol typical of the protocols used for testing life of EndoWrist instruments?

MS. CAHOY: Objection to form.

THE WITNESS: This protocol is typical of our final V&V test of our instruments.

BY MR. SINDONI:

Q. Okay. If I could direct your attention to Section 5.2 on the first page and the second paragraph in that section.

Could you read that first sentence for me.

A. The second paragraph?

Q. Yes, beginning with, "A 'life use' . . . ."

A. [As read]: "A 'life use' for the instrument is defined by the clinical simulation procedure that was developed by clinical marketing."

Q. And what is clinical marketing?

A. So an interesting time in Intuitive's life cycle. We were talking earlier today about a clinical development engineering function. There was a time in Intuitive's history that our clinical development function sat within our marketing organization, and those engineers worked with

marketing. And it's my recollection that this refers to that.

Q. And could you read the first sentence of the paragraph in Section 5.3.

A. [As read]: "A life rating for each instrument is defined by the Clinical life simulation surgical maneuver tasks that were developed by Marketing and clinical engineering for the instrument type."

Q. And is that consistent with your understanding of how the life rating for the instrument would have been defined in this protocol?

MS. CAHOY: Objection to form.

THE WITNESS: My recollection on how this occurred is the marketing and clinical engineering functions were the ones that were closest to our users. And they were the ones that were in the field and brought that insight back into -- so that we could optimize the usage of the instrument.

BY MR. SINDONI:

Q. And could I turn your attention -- and, again, as I said, as we flip through the document, if you need time, let me know -- to page 4, Section 12.1.

A. Yes.

A. That may happen or a problem may arise during the procedure.

Q. And when an EndoWrist is used during a procedure and it doesn't function properly, does it always result in injury to a patient?

MS. CAHOY: Objection to form.

THE WITNESS: No.

BY MR. SINDONI:

Q. Under some circumstances, it does, correct, but not always? Under some circumstances it does, but not always; is that correct?

A. We try -- we look to minimize any potential patient injury. And so not all of them do, but they could. And it's why we take instrument failure seriously.

Q. Okay. And what happens when the instrument fails during a procedure and it results in injury to the patient?

MS. CAHOY: Objection to form.

THE WITNESS: All -- we encourage all of our customers, as well as all of our -- well, Intuitive encourages all of customers, as well as employees, to report any device issues, as well as any patient issues. And that happens through our complaint process.

Are you aware of whether anyone has been able to bypass that usage counter?

A. Yes.

Q. Do you recall when you first became aware that someone was able to bypass that usage counter?

A. If I recall correctly, one of our failure analysis technicians, through the RMA failure analysis process, opened up one of our instruments and found it modified with additional components.

And that was one of the initial triggers that had us looking into what may be happening when these instruments were being modified, and that's when we learned about bypassing the instrument counter.

Q. Do you recall when that was?

A. Not a precise date. It was a few years ago.

Q. Do you recall what position you were in at Intuitive when that occurred?

A. That's a great question. Probably -- probably product quality is what I'm guessing, maybe post-market before product quality. It was -- yeah, I don't recall exactly.

Q. Prior to encountering that instrument that you referred to, did you personally have any

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

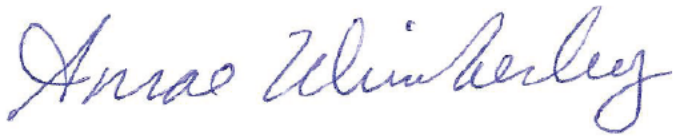
That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were administered an oath; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript ( ) was (X) was not requested.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney of any party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: October 13, 2022



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